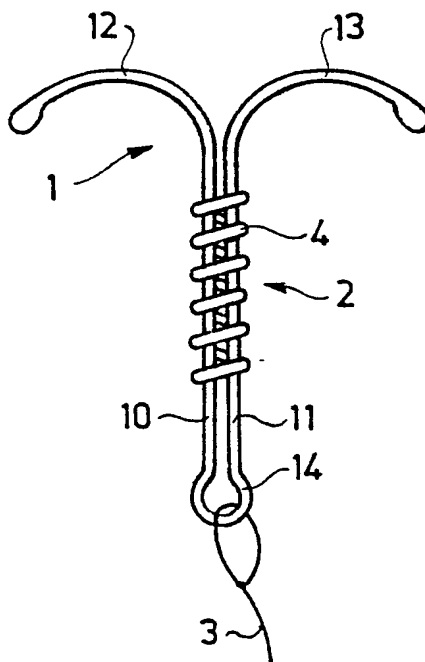




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(21) International Application Number: PCT/HU90/00009 (22) International Filing Date: 23 January 1990 (23.01.90) (30) Priority data: 569/89 7 February 1989 (07.02.89) HU (71) Applicant (for all designated States except US): RADELKIS ELEKTROKÉMIAI MŰSZERGYÁRTÓ IPARI SZÖV- ETKEZET [HU/HU]; P.O. Box 106, H-1300 Budapest (HU). (72) Inventors; and (75) Inventors/Applicants (for US only) : HAVAS, Jenő [HU/ HU]; Remetehegyi u. 32, H-1037 Budapest (HU). TAK- ÁCS, Ferenc [HU/HU]; Naphegy u. 59, H-1016 Budap- est (HU).		(74) Agent: DANUBIA; P.O. Box 198, H-1368 Budapest (HU). (81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BG, BR, CA, CH, CH (European patent), DE, DE (European patent), DK, DK (European patent), ES, ES (European patent), FI, FR (European patent), GB, GB (European patent), IT (European pa- tent), JP, KP, KR, LK, LU, LU (European patent), MC, MG, MW, NL, NL (European patent), NO, RO, SD, SE, SE (European patent), SU, US. Published <i>With international search report.</i>

(54) Title: INTRAUTERINE CONTRACEPTIVE DEVICE**(57) Abstract**

The present invention refers to an intrauterine contraceptive device comprising an active body (2) of a metallic substance of contraceptive activity, carrier means (1) for supporting the active body (2) in an intrauterine environment. The essence of this invention is that the active body (2) is made of at least two metals forming a plurality of galvanic cells in the intrauterine environment.

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INTRAUTERINE CONTRACEPTIVE DEVICE

5

FIELD OF THE INVENTION

The present invention refers to an intrauterine contraceptive device comprising an active body made of a
10 metallic substance of contraceptive activity and carrier means made of a biologically inert substance for supporting the active body in an intrauterine environment, wherein the carrier means are generally made of a plastic and connected with an indicator thread.

15

BACKGROUND OF THE INVENTION

The contraceptive effectiveness of some intraurethine devices has been known since many years. They have found
20 application from the end of the sixties, when the appropriate plastics were prepared and investigated. Since that time the intrauterine devices have become applicable in a wide selection of different shapes, configurations and materials.

25

The process of the development of the intrauterine contraceptive devices can be shared into three periods. The first of them is marked by the application of the appropriate plastics (see e.g. US-PS 3.937.217), completed in the second period by a steroid-releasing substance. The
30 third period is characterized in introducing copper for preparing the active body. The intrauterine devices based on copper comprise carrier means, generally made in T-shape from plastic (e.g. polyethylene) material, an active body made in form of a copper wire contacting the carrier means,
35 further an indicator thread fixed on the carrier means.

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Mostly, the active body is a coil shaped element and the indicator thread is a flexible line made of plastic (e.g. polyamid).

The contraceptive effectiveness of the known intra-
5 uterine devices comprising a copper wire is much higher than that of the devices prepared without any active substance. This recognition is based on different systematic investigations. One of them is reported by I. Batár in the Orvosi Hetilap (Hungarian Medicine Weekly, 2237,
10 129., 1988, in Hungarian). The effectiveness, rather to be called ineffectiveness of the intrauterine devices made with a copper wire (Type Multiload Cu 250) and those made without any active substance (so-called Szontágh's device produced in Hungary) were compared. The quantitative data
15 were analysed by computing the so-called netto cumulative termination rates introduced by C. Tietze and S. Lewit (Stud. in Fam. Plann., 35, 4., 1973) and accepted in the international practice: the effectiveness is measured on the basis of the number of women concepting within the
20 period of one year among hundred having the intrauterine device. The corresponding data are: 2.2 for the Multiload Cu 250 device and 3.9 for the Szontágh's device, i.e. the first of the devices offers much higher contraceptive safety than the second one. In the article of I. Batár no
25 analyse upon the merits of the technical features of the intrauterine devices can be found.

In the article mentioned above the clinical observations continued over a period of about ten years are reported, too. The contraceptive intrauterine devices comprising active bodies made with a copper wire were used by
30 1446 women and the so-called cumulative pregnancy rate appeared to be 6.9. Because of 88 conceptions in the period observed the ineffectiveness was as high as 6.1 %. Other literature data (cited e.g. in Population Reports, Volume
35 X, 4., B103 to B135, 1985, Baltimore, USA) show similar in-

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effectiveness. The investigations carried out in some Latino-American countries gave the following characteristic data: the pregnancy rate was 5 % for the women using intrauterine devices including copper, 8 % in the women population taking oral contraceptives, 18 % in that applying mechanical contraceptives (condoms) and 40 % in the women population making no use of contraceptives.

In 1987 the proposal of S. G. Kaali, specializing in gynaecology in the Women's Medical Pavilion (Dobbs Ferry, New York, USA) became known for inactivating the spermatozoa in the uterus by the means of a weak electric current. The Kaali's contraceptive device hasn't been tested in human body, in any case, no such data were available prior to filing the present application; it consists of metallic electrodes arranged in the uterus and a battery connected with the electrodes.

The investigations have given a permanent evidence that the contraceptive effectiveness of the known intrauterine devices made with a copper wire forming an active body is as high as 94 to 95 % and this is a relatively low level when compared to 100 % assigned to the full safety. An improvement of the effectiveness is therefore highly desired.

A further drawback of the known intrauterine devices lies in that the copper material of the active body is slowly dissolving and consequently the active body during its presence in the human body fragmentates. The fragmentated copper wire can harm thereby the tissues and has shortened life period. For avoiding the consequences of this drawback the U.S. Letters Patent 4 351 326 proposed to prepare the active body in form of a copper wire having a core consisted of a metal nobler than copper. The firm Schering AG (FRG) produces an intrauterine contraceptive device of this kind under the name NOVA T, wherein the core of the copper wire is made of silver. In this way the

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surface of the intrauterine device retains its required smoothness longer time than in the case of pure copper wires.

5 The contraceptive effect of the intrauterine devices comprising copper is supposed to be attributed even to copper. The dissolution process of copper, i.e. the speed of producing copper ions by the device is uneven, and therefore the known devices have a not stabilized influence on the physiological processes taking place in the human
10 body (i.e. the enzyme processes, glycogen metabolism, absorption of estrogens, activity of the uterine muscles, changes in the composition of the fluids etc.), the influence on the mechanism of preventing the pregnancy, the implantation of the fertilized ovum.

15

SUMMARY OF THE INVENTION

The present invention is intended to creating an intrauterine contraceptive device of high contraceptive effectiveness reaching at least 99 % based on a metallic
20 substance. The intrauterine device proposed by the invention should preserve its original shape during the whole period of application and ensure a uniform deliberation of the ions having contraceptive effect.

25 The invention is based on the recognition that the active body of the intrauterine device should be made of an appropriate metal composition containing at least two metals forming one with another a galvanic cell in the intrauterine environment.

30 Based on the recognition recited above an intrauterine contraceptive device has been created, which comprises an active body consisting of a metallic substance of contraceptive activity and carrier means made of a biologically inert substance for supporting the active body
35 in an intrauterine environment, wherein according to the

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invention the active body is made of a metallic substance including at least two metals forming a plurality of local galvanic cells in the intrauterine environment. The active body is advantageously made at least partially of an alloy of the at least two metals.

The plurality of the galvanic cells is advantageously consisted of a copper-gold or a copper-zinc-silver alloy. Of course, other alloys can be applied, too, and it is especially desirable to prepare the active body from copper and at least one metal of higher electropositivity, when copper forms the anode of the galvanic cell and the other metal, e.g. gold or silver constitutes the cathode thereof. Some other metal composition are: nickel and gold, copper, silver and zinc, silver and cadmium, silver and palladium.

The basic feature of the intrauterine device of the invention is that the active body includes a plurality of small, in most cases microscopic galvanic cells wherefrom the ions of the anode, generally the copper ions can be dissolved with higher concentration than from the intrauterine devices of known designs.

The active body of the intrauterine contraceptive device proposed by the invention can preferably be made in the shape of a coil consisting of the mixture of more metals (e.g. copper is completed with zinc and silver), wherein the mixture can constitute an alloy, too, if required. In this way more metals can be present in ionic form and in controlled amounts, whereby the potential difference between the electrodes of the galvanic cells is stepwise increased and the effectiveness of the contraceptive activity possibly based on inactivating the spermatozoa is increased.

Another preferred embodiment of the active body is when prepared in tubular shape, wherein one or more tubular elements are applied. In the case of more tubular elements

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they can be divided by ring shaped elements.

BRIEF DESCRIPTION OF THE DRAWINGS

- 5 Further advantages and features of the intrauterine contraceptive device proposed by the invention will be shown in more detail with reference to the accompanying drawings presenting by way of examples some preferred em-
10 bodiments of the device. In the drawings
- FIG. 1 is a schematic view of a proposed contracep-
tive device with coil shaped active body,
FIG. 2 is the schematic view of an intrauterine con-
traceptive device including a tubular shaped
active body made from an alloy sheet, and
15 FIG. 3 is the schematic view of an intrauterine con-
traceptive device with an active body in form
of two tubular and three ring form elements.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

- 20 As it is apparent from FIGS 1, 2 and 3 the proposed intrauterine contraceptive device of the invention consists of carrier means 1 made of plastic, an active body 2 of required activity exerted e.g. by inactivating spermato-
zoa in an intrauterine environment and an indicator thread
25 3 connected to the carrier means 1 (FIGs. 1, 2 and 3.)

- The carrier means 1 consist generally of an appropriate plastic which usually has no physiological activity in the intrauterine environment. The feature that the carrier means 1 are biological inert is, however, not a
30 feature following from the contraceptive effectiveness of the active body 2 and if required, the carrier means 1 can be completed by further substances of appropriate activity. The carrier means 1 is generally a T-shaped, two arm element which can be arranged in the uterus of a woman and
35 is intended to support the active body 2.

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The carrier means 1 generally consist of two stems 10 and 11 connected to one another in a loop 14 carrying the indicator thread 3 and continued in respective arms 12 and 13 (FIG. 1).

5 The active body 2 of the proposed intrauterine device is generally produced in form of a coil 4 wound around the two stems 10 and 11 of the carrier means 2 (FIG. 1). The coil 4 can be also a double helix prepared from a wire by the means of known mechanical technologies. The
10 simple coil 4 or the double helix, i.e. a coil wound from another coil prepared from a wire offer high surface area.

Another possibility of shaping the active body 2 is shown in FIG. 2., wherein the active body 2 consists of a tube 5 surrounding the two stems 10 and 11 from the loop 14
15 up to the beginning of the arms 12 and 13. The tube 5 can be produced by forming a metallic sheet to a tubular element and closing, e.g. by welding the metallic sheet along the lines of connecting the edges of the sheet to one another.

20 A yet further preferred possibility can be seen in FIG. 3., wherein an active body 2 is divided into more parts: the stems 10 and 11 are partly covered by tubular elements 7 and a ring 6 arranged therebetween. Further rings 8 are placed at the free ends of the respective arms
25 12 and 13. This solution is especially advantageous when the active body 2 consists of sheet- and wire-like elements with inhomogenized surface layer including the at least two metals forming microscopic or small galvanic cells as required by the invention. The two or more metal composition
30 is also a requirement against the coil 4 and the tube 5, made in whole volume or at least on the outer surface of at least two metals.

Generally, the active body 2 includes copper and at least one further metal of higher electropositivity, e.g.
35 gold or silver. These metals can form either a mixture or

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an alloy. A third and further metal can be applied, too, and in this way a series of galvanic cells of different voltages is applied. Other preferred selections for preparing the active body 2 are listed up in the examples given below, however, it is not intended to be limited by the examples.

In the intrauterine environment the proposed contraceptive device forms a plurality of galvanic cells with electrodes in the active body 2. The electrolyte is the biologic fluid of the uterus. If the active body is made of a given first metal, e.g. copper and a more noble metal, e.g. gold the rules of the electrochemical corrosion predict that the anodes are at the "isles" formed by the first metal, i.e. copper and the cathodes at the parts consisted of the nobler metal, i.e. gold. The dissolution process results in removing first metal from the active body 2 and the cathodes remain practically without change on their original places, their fragmentation can not be observed. In the galvanic cells the concentration of the first metal ions, i.e. the copper ions is higher than in the environment of the known intrauterine devices.

Because of applying a mixture or alloy containing at least two metals the process of deliberating the ions ensuring the contraceptive activity of the proposed device becomes controlled, the cathodes or cathode isles ensure retaining the original shape of the active body 2 and the problems linked with the fragmentation of the active body 2 resulting in rough, splintered outer surface thereof in the known devices can be avoided. The composition of the mixture or alloy of the active body 2 can be selected in a wide range including more orders of magnitudes.

The proposed intrauterine contraceptive devices operate in the following way: The small or microscopic galvanic cells created by the component metals of the active

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body 2 are capable not only of deliberating the required active ions in the intrauterine environment but also of generating an electric field. Therefore the contraceptive activity supposed to be based on chemical effects is intensively improved by the electric field. It is known that the spermatozoa have electric charge and this results in their migration to the cathodes and anodes of the galvanic cells, respectively, according to their electric charges. Thereby the inactivating process of the spermatozoa shows higher effectiveness than in the known devices.

A further advantage of the proposed intrauterine contraceptive devices lies in the fact that during the excitation accompanying the sexual intercourse, when the temperature of the human body exceeds the normal level, the intensity of deliberating ions in the galvanic cells increases what results in higher activity of the proposed intrauterine contraceptive device when this is especially required.

Further some examples will be shown:

20

EXAMPLE 1.

The active body 2 of the intrauterine device proposed by the invention is a coil 4 (FIG. 1.) consisting of 85 parts copper and 15 parts gold. The coil 4 is wound from a wire and surrounds the carrier means 1 made of polyethylene. The carrier means 1 are connected with a polyamide thread 3.

25

EXAMPLE 2.

The active body 2 of the intrauterine device proposed by the invention is a coil 4 (FIG. 1.) consisting of an alloy including 30 parts zinc and 70 parts copper. The coil 4 is wound from a wire and surrounds the carrier means 1 made of polyethylene. The carrier means 1 are connected with a polyamide thread 3.

30

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EXAMPLE 3.

The active body 2 of the intrauterine device proposed by the invention is a coil 4 (FIG. 1.) consisting of an alloy including 40 parts palladium and 70 parts silver.

5 The coil 4 is wound from a wire and surrounds the carrier means 1 made of polyethylene. The carrier means 1 are connected with a polyamide thread 3.

EXAMPLE 4.

10 The active body 2 of the intrauterine device proposed by the invention is a coil 4 (FIG. 1.) consisting of an alloy including 18 parts nickel and 82 parts gold. The coil 4 is wound from a wire and surrounds the carrier means 1 made of polyethylene. The carrier means 1 are connected with a polyamide thread 3.

15 EXAMPLE 5.

The active body 2 is a tube 5 (FIG. 2.) made of an alloy consisting of 40 parts copper, 25 parts silver and 35 parts zinc. The tube 5 is prepared by welding from a metal sheet. The carrier means 1 made of plastic are connected

20 with a polyamide thread 3.

EXAMPLE 6.

The active body 2 is made of a copper wire and a copper sheet with having surface layer including gold mixed with copper. The wires are prepared in the form of the

25 rings 6 and 8, the sheet is closed to constitute the tubular elements 7 (FIG. 3). The carrier means 1 made of plastic are connected with a thread 3 consisting of a flexible plastic.

30 EXAMPLE 7.

The active body 2 is made of a wire and a sheet made of an alloy consisting of 90 parts silver and 10 parts cadmium. The wires are prepared in the form of the rings 6

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and 8, the sheet is closed to constitute the tubular elements 7 (FIG. 3). The carrier means 1 made of plastic are connected with a thread 3 consisting of a flexible plastic.

5 The intrauterine contraceptive devices of the invention were investigated in conditions near to the physiological. According to the observations the effective life is more than 20 years and the contraceptive effectiveness is as high as at least 99 %. The device can be applied in a fully
10 similar way to the known devices.

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WHAT WE CLAIM IS:

- 5 1. An intrauterine contraceptive device, comprising
 (a) an active body made of a metallic substance of contra-
 ceptive activity,
 (b) carrier means for supporting said active body in an in-
 trauterine environment,
10 characterized in that
 said active body (2) is made of at least two metals forming
 a plurality of galvanic cells in said intrauterine environ-
 ment.
2. The contraceptive device as set forth in claim 1,
15 characterized in that
 said active body (2) consists at least partially of an al-
 loy consisting of said at least two metals.
3. The contraceptive device as set forth in claim 1
20 or 2, characterized in that
 said active body (2) is made from a mixture and/or alloy
 including at least one metal selected from the group com-
 prising zinc, copper, nickel, silver and cadmium, and at
 least one metal more noble than that selected from said
 group.
- 25 4. The contraceptive device as set forth in claim 3,
 characterized in that
 said more noble metal is selected from the group compris-
 ing silver, gold and palladium.
5. The contraceptive device as set forth in claim 3
30 or 4, characterized in that
 said mixture and/or alloy comprises zinc.
6. The contraceptive device as set forth in any pre-
 cedent claim, characterized in that
 said active body (2) is made in form of a coil (4) wound a-
 round said carrier means (1).

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7. The contraceptive device as set forth in any precedent claim, characterized in that said active body (2) is made at least partially in form of a tubular element (5, 7) arranged along stems (10, 11) of said carrier means (1).

8. The contraceptive device as set forth in claim 7, characterized in that said active body (2) consists of at least two tubular elements (7) surrounding said carrier means (1).

9. The contraceptive device as set forth in claim 8, characterized in that said active body (2) consists of two tubular elements (6) and three rings (6, 8), wherein one ring is arranged on said stems (10, 11) and two are placed on arms (12, 13) of said carrier means (1).

10. An intrauterine contraceptive device, comprising (a) an active body made of a metallic substance of contraceptive activity and (b) carrier means for supporting said active body in an intrauterine environment, said carrier means being made of a plastic,

characterized in that said active body (2) is made of a metallic element consisting of a metal selected from the group comprising zinc, copper, cadmium, nickel and silver and at least one metal of electropositivity higher than that of the metal selected from said group, said metals forming a mixture and/or an alloy, wherein said mixture and/or alloy of said metals constitute a plurality of galvanic cells in the intrauterine environment.

11. The contraceptive device as set forth in claim 11, characterized in that said metallic element comprises said at least one metal selected from the group consisting of silver, palladium and gold.

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12. The contraceptive device as set forth in claim 11 or 12, characterized in that said metal selected from said group is copper, and said metallic element is made with a further metal of electropositivity lower than that of copper, said further metal being particularly zinc.

13. The contraceptive device as set forth in any of claims 11 to 13, characterized in that said active body (2) is shaped to form a coil (4) and/or at least one tubular element (5, 7).

14. The contraceptive device as set forth in claim 15, characterized in that said active body (2) includes at least one ring (6, 8) surrounding said carrier means (1).

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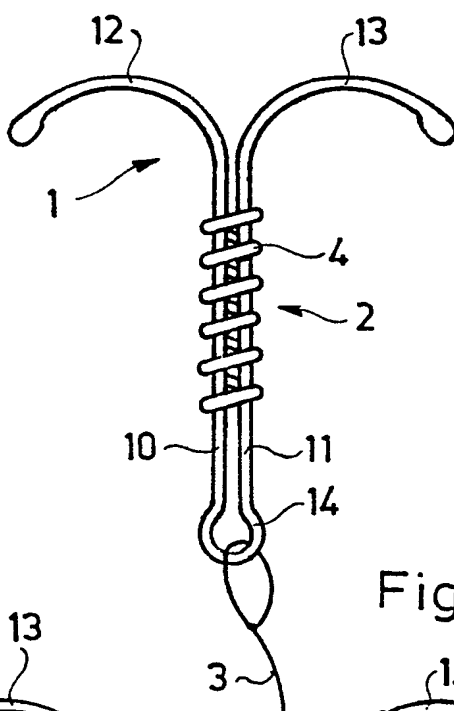


Fig. 1

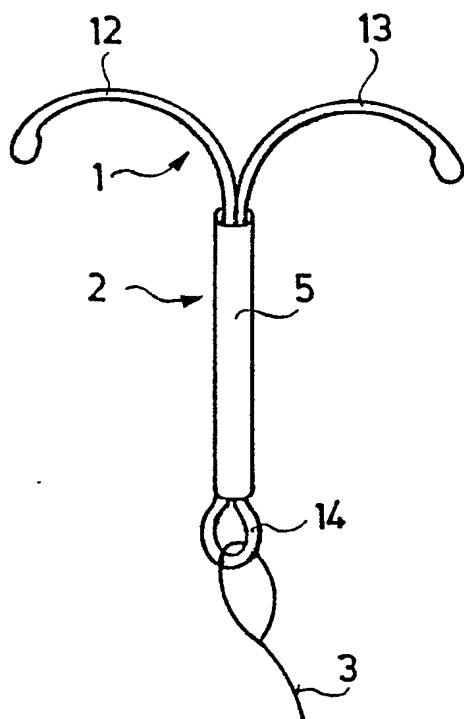


Fig. 2

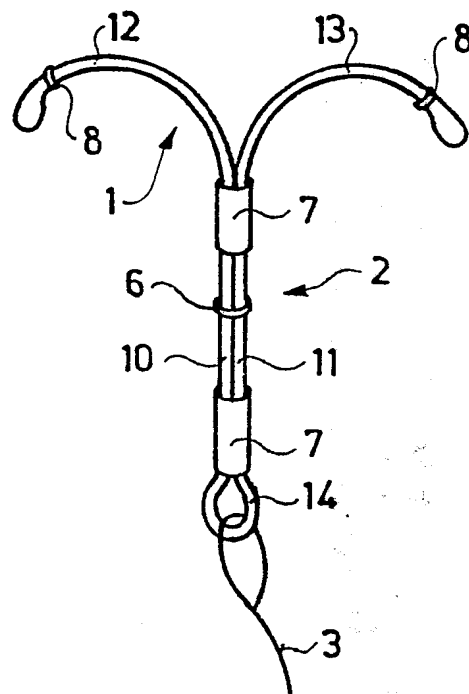


Fig. 3

INTERNATIONAL SEARCH REPORT

International Application No PCT/HU 90/00009

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC IPC ⁵ : A 61 F 6/14		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
Int.Cl. ⁵ :	A 61 F 6/00, 6/06, 6/14, 6/18.	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹		
Category ⁹	Citation of Document, ¹¹ with Indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
A	US, A, 4 353 363 (SOPENA QUESADA) 12 October 1982 (12.10.82), see abstract; claim 1; fig. 1-3.	(1,3,6,10, 12,13)
A	US, A, 4 655 204 (BASUYAUX) 07 April 1987 (07.04.87), see column 2, line 53 - column 3, line 5; fig. 1.	(1,3,6,10, 12,13)
A	DE, A1, 2 758 037 (HERTEN KURT) 28 June 1979 (28.06.79), see page 9, line 2 - page 10, line 17; fig.	(1,3,7,10, 12,13)
A	US, A, 4 351 326 (KOSONEN) 28 September 1982 (28.09.82), see column 1, lines 41-61.	(1-4,6,10, 13)

<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>¹⁰ Special categories of cited documents: ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search		Date of Mailing of this International Search Report
29 March 1990 (29.03.90)		03 April 1990 (03.04.90)
International Searching Authority		Signature of Authorized Officer
AUSTRIAN PATENT OFFICE		

Anhang zum internationalen Recherchenbericht über die internationale Patentanmeldung Nr.

In diesem Anhang sind die Mitglieder der Patentfamilien der im obengenannten internationalen Recherchenbericht angeführten Patentedokumente angegeben. Diese Angaben dienen nur zur Unterrichtung und erfolgen ohne Gewähr.

Annex to the International Search Report on International Patent Application No. PCT/HU 90/00009

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned International search report. The Austrian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Annexe au rapport de recherche internationale relatif à la demande de brevet international n°.

La présente annexe indique les membres de la famille de brevets relatifs aux documents de brevets cités dans le rapport de recherche internationale visé ci-dessus. Les renseignements fournis sont donnés à titre indicatif et n'engagent pas la responsabilité de l'Office autrichien des brevets.

Im Recherchenbericht angeführtes Patent- dokument Patent document cited in search report Document de brevet cité dans le rapport de recherche	Datum der Veröffentlichung Publication date Date de publication	Mitglied(er) der Patentfamilie Patent family member(s) Membre(s) de la famille de brevets	Datum der Veröffentlichung Publication date Date de publication
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